

Current Listing of Claims

1. (currently amended) A method for evaluating the glycosylated hemoglobin (HbA_{1c}) of a patient based on blood glucose (BG) data collected over a first predetermined duration, said method comprising:
~~preparing the data for estimating HbA_{1c} using a predetermined sequence of mathematical formulas defined as:~~
pre-processing [[of]] the collected BG data to
convert the collected BG data into derived BG
data derived from said collected BG data,
estimating HbA_{1c} by applying at least one ~~of four~~
predetermined formula[[s]] to said derived BG
data, [[and]]
validating ~~validation of~~ the estimate via sample
selection criteria;
electronically transforming the estimate into a
visual depiction; and
outputting the visual depiction of the estimate
to a user.
2. (original) The method of claim 1, wherein said first predetermined duration is about 60 days.
3. (original) The method of claim 1, wherein said first predetermined duration ranges from about 45 days to about 75 days.
4. (original) The method of claim 1, wherein said first predetermined duration ranges from about 45 days to

about 90 days.

5. (currently amended) The method of claim 1, wherein the pre-processing of the data ~~for each patient~~ comprises: conversion of plasma data to whole blood BG mg/dl; conversion of BG measured in mg/dl to units of mmol/l; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1).

6. (previously presented) The method of claim 1, wherein the preprocessing of the data ~~comprises for each patient using predetermined mathematical formulas is defined as:~~

conversion of plasma to whole blood BG mg/dl via $BG = PLASBG \text{ (mg/dl)} / 1.12$;

conversion of BG measured in mg/dl to units of mmol/l via $BGMM = BG / 18$; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

$Scale = [\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

$Risk1 = 22.765(Scale)^2$, wherein

$RiskLO = Risk1$ if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise $RiskLO = 0$, and

$RiskHI = Risk1$ if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise $RiskHI = 0$,

BGMM1 = average of BGMM per patient,
RLO1 = average of RiskLO per patient,
RHI1 = average of RiskHI per patient,
LO6 = average of RiskLO computed only for
readings during the night, otherwise missing if
there are no readings at night,
N06, N12, N24 are percentage of SMBG readings in
time intervals ,
NC1 = total number of SMBG readings in the first
predetermined duration; and
NDAYS = number of days with SMBG readings in the
first predetermined duration.

7. (original) The method of claim 6, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.
8. (original) The method of claim 6, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:

if (RHI1 is \leq about 5.25 or if RHI1 is \geq about 16)
then the assigned group= 0,
if (RHI1 is $>$ about 5.25 and if RHI1 is $<$ about
7.0) then the assigned group=1,
if (RHI1 is \geq about 7.0 and if RHI1 is $<$ about 8.5
) then the assign group=2, and
if (RHI1 is \geq about 8.5 and if RHI1 is $<$ about 16)

then the assigned group=3.

9. (original) The method of claim 8, comprising providing estimates using a predetermined mathematical formula defined as:

$$E0 = 0.55555 * BGMM1 + 2.95,$$

$$E1 = 0.50567 * BGMM1 + 0.074 * L06 + 2.69,$$

$$E2 = 0.55555 * BGMM1 - 0.074 * L06 + 2.96,$$

$$E3 = 0.44000 * BGMM1 + 0.035 * L06 + 3.65; \text{ and}$$

if (Group = 1) then EST2=E1, or if (Group = 2)
then EST2=E2, or if (Group = 3) then EST2=E3,
otherwise EST2=E0.

10. (original) The method of claim 9, comprising providing further correction of the estimates using a predetermined mathematical formula defined as:

if (missing(L06)) EST2=E0,

if (RLO1 is \leq about 0.5 and RHI1 is \leq about 2.0)
then EST2=E0-0.25,

if (RLO1 is \leq about 2.5 and RHI1 is $>$ about 26)
then EST2=E0-1.5*RLO1, and

if ((RLO1/RHI1) is \leq about 0.25 and L06 is $>$ about
1.3) then EST2=EST2-0.08.

11. (currently amended) The method of claim 10 for estimating the HbA_{1c} of a patient based on BG data collected over the first predetermined duration, ~~said method comprising:~~

said estimating HbA_{1c} using said at least one of four
predetermined mathematical formulas defined as
comprising:

- a) $HbA_{1c} =$ the EST2 defined by claim 8 or as corrected by claim 10 or
- b) $HbA_{1c} = 0.809098 * BGMM1 + 0.064540 * RLO1 - 0.151673 * RHI1 + 1.873325$, wherein
BGMM1 is the average BG (mmol/l) of claim 6.
RLO1 is the Low BG Index of claim 6.
RHI1 is the High BG Index of claim 6; or
- c) $HbA_{1c} = 0.682742 * HBA0 + 0.054377 * RHI1 + 1.553277$, wherein
HBA0 is a previous reference HbA1c reading taken about a second predetermined period prior to the estimate, wherein
RHI1 = is the High BG Index of claim 6; or
- d) $HbA_{1c} = 0.41046 * BGMM1 + 4.0775$
wherein BGMM1 is the average BG (mmol/l) of claim 6.
12. (original) The method of claim 11, wherein said second predetermined duration is about three months.
13. (original) The method of claim 11, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.
14. (original) The method of claim 11, wherein said second predetermined duration ranges from about 2.5 months to six months.
15. (currently amended) The method of claim 11, wherein the validation of the HbA_{1c} estimate using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

- a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;
 - b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;
 - c) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio $(RL01/RH11) \geq$ about 0.005),
wherein
RL01 is the Low BG Index of claim 6
RH11 is the High BG Index of claim 6; or
 - d) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio $(N06 \geq$ about 3%).
wherein
N06 is the percentage of readings during the night of claim 6.
16. (original) The method of claim 15, wherein said third predetermined duration is at least 35 days.
17. (original) The method of claim 15, wherein said third predetermined duration ranges from about 35 days to about 40 days.
18. (original) The method of claim 15, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.

19. (currently amended) A system for evaluating the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

~~prepare the data for estimating HbA_{1c} using a predetermined sequence of mathematical formulas defined as:~~

pre-process the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data,

estimate HbA_{1c} by applying at least ~~one of four~~ predetermined formula[[s]] to said derived BG data, [[and]]

validate the estimate via sample selection criteria; and

output the estimate to a user.

20. (original) The system of claim 19, wherein said first predetermined duration is about 60 days.
21. (original) The system of claim 19, wherein said first predetermined duration ranges from about 45 days to about 75 days.
22. (original) The system of claim 19, wherein said first predetermined duration ranges from about 45 days to about 90 days.
23. (currently amended) The system of claim 19, wherein

the preprocessing of the data ~~for each patient~~
comprises:

conversion of plasma to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l;
and

computing Low Blood Glucose Index (RL01) and High
Blood Glucose Index (RHI1).

24. (currently amended) The system of claim 19, wherein
the preprocessing of the data ~~for each patient using
predetermined mathematical formulas is defined as
comprises:~~

conversion of plasma to whole blood BG mg/dl via
 $BG = PLASBG \text{ (mg/dl)} / 1.12$;

conversion of BG measured in mg/dl to units of mmol/l)
via $BGMM = BG / 18$; and

computing Low Blood Glucose Index (RL01) and High
Blood Glucose Index (RHI1) using a predetermined
mathematical formula defined as:

$Scale = [\ln(BG)]^{1.0845} - 5.381$, wherein BG is
measured in units of mg/dl,

$Risk1 = 22.765(Scale)^2$, wherein

$RiskLO = Risk1$ if (BG is less than about 112.5) and
therefore risk of LBGI exists, otherwise
 $RiskLO = 0$, and

$RiskHI = Risk1$ if (BG is greater than about 112.5)
and therefore risk of HBGI exists, otherwise
 $RiskHI = 0$,

$BGMM1 = \text{average of BGMM per patient,}$

RL01 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

25. (original) The system of claim 24, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.
26. (original) The system of claim 24, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:

if (RHI1 is \leq about 5.25 or if RHI1 is \geq about 16)
then the assigned group= 0,

if (RHI1 is $>$ about 5.25 and if RHI1 is $<$ about 7.0) then the assigned group=1,

if (RHI1 is \geq about 7.0 and if RHI1 is $<$ about 8.5) then the assign group=2, and

if (RHI1 is \geq about 8.5 and if RHI1 is $<$ about 16)
then the assigned group=3.

27. (original) The system of claim 26, comprising providing estimates using a predetermined mathematical formula defined as:

$$E0 = 0.55555 * BGMM1 + 2.95,$$

$$E1 = 0.50567 * BGMM1 + 0.074 * L06 + 2.69,$$

$$E2 = 0.55555 * BGMM1 - 0.074 * L06 + 2.96,$$

$$E3 = 0.44000 * BGMM1 + 0.035 * L06 + 3.65; \text{ and}$$

if (Group = 1) then EST2=E1, or if (Group = 2)
then EST2=E2, or if (Group = 3) then EST2=E3,
otherwise EST2=E0.

28. (original) The system of claim 27, comprising providing further correction of the estimates using a predetermined mathematical formula defined as:

if (missing(L06)) EST2=E0,

if (RL01 is \leq about 0.5 and RHI1 is \leq about 2.0)
then EST2=E0-0.25,

if (RL01 is \leq about 2.5 and RHI1 is $>$ about 26)
then EST2=E0-1.5*RL01, and

if ((RL01/RHI1) is \leq about 0.25 and L06 is $>$ about
1.3) then EST2=EST2-0.08.

29. (currently amended) The system of claim 28 for estimating the HbA_{1c} of a patient based on BG data collected over the first predetermined duration, ~~said system comprising:~~

wherein said estimating HbA_{1c} comprises ~~using said at least one of four predetermined mathematical formulas defined as:~~

a) HbA_{1c}~~1c~~ = the EST2 defined by claim 8 or as

corrected by claim 10 or

- b) $HbA_{1c} = 0.809098 * BGMM1 + 0.064540 * RLO1 - 0.151673 * RHI1 + 1.873325$, wherein

BGMM1 is the average BG (mmol/l) of claim 24,

RLO1 is the Low BG Index of claim 24,

RHI1 is the High BG Index of claim 24; or

- c) $HbA_{1c} = 0.682742 * HBA0 + 0.054377 * RHI1 + 1.553277$, wherein

HBA0 is a previous reference HbA_{1c} reading taken about a second predetermined period prior to the estimate, wherein

RHI1 = is the High BG Index of claim 24; or

- d) $HbA_{1c} = 0.41046 * BGMM1 + 4.0775$

wherein BGMM1 is the average BG (mmol/l) of claim 24.

30. (original) The system of claim 29, wherein said second predetermined duration is about three months.
31. (original) The system of claim 29, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.
32. (original) The system of claim 29, wherein said second predetermined duration ranges from about 2.5 months to six months.
33. (currently amended) The system of claim 29, wherein the validation of the HbA_{1c} estimate using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

- a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;
 - b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;
 - c) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio $(RL01/RH11) \geq$ about 0.005),
wherein
RL01 is the Low BG Index of claim 24,
RH11 is the High BG Index of claim 24; or
 - d) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio $(N06 \geq$ about 3%),
wherein
N06 is the percentage of readings during the night of claim 24.
34. (original) The system of claim 33, wherein said third predetermined duration is at least 35 days.
35. (original) The system of claim 33, wherein said third predetermined duration ranges from about 35 days to about 40 days.
36. (original) The system of claim 33, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.

37. (currently amended) A system for evaluating the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient;

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

~~prepare the data for estimating HbA_{1c} using a predetermined sequence of mathematical formulas defined as:~~

pre-process the acquired BG data to
convert the acquired BG data into
derived BG data derived from said
acquired BG data;

estimate HbA_{1c} by applying at least one
~~of four~~ predetermined formula[[s]] to
said derived BG data; [[and]]

validate the estimate via sample
selection criteria; and

output the estimate to a user.

38. (currently amended) A computer program product comprising a tangible computer readable ~~usable~~ medium having computer program logic for enabling at least one processor in a computer system to evaluate the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said

computer program logic comprising:

~~preparing the data for estimating HbA_{1c} using a
predetermined sequence of mathematical formulas
defined as:~~

pre-processing of the collected BG data to
convert the collected BG data into derived
BG data derived from said collected BG data,
estimating HbA_{1c} by applying at least one ~~of~~
~~four~~ predetermined formula[[s]] to said
derived BG data, and
validation of the estimate via sample
selection criteria; and

outputting the estimate to a user.

39. (original) The computer program product of claim 38,
wherein said computer program logic further comprises
the steps of claim 11.

40. (withdrawn) A method for evaluating the long term
probability for severe hypoglycemia (SH) and/or
moderate hypoglycemia (MH) of a patient based on BG
data collected over a predetermined duration, said
method comprising:

computing LBGI based on said collected BG data;
and

estimating the number of future SH episodes using
a predetermined mathematical formula based on
said computed LBGI.

41. (withdrawn) The method of claim 40, wherein:

said computed LBGI is mathematically defined from a

series of BG readings x_1, x_2, \dots, x_n taken at time points t_1, t_2, \dots, t_n as:

$$LBGI = \frac{1}{n} \sum_{i=1}^n lbgi(x_i; 2)$$

where:

$lbgi(BG; a) = 10 \cdot f(BG)^a$ if $f(BG) > 0$ and 0 otherwise,

a = about 2, representing a weighting parameter.

42. (withdrawn) The method of claim 40, further comprising:
 - defining predetermined risk categories(RCAT), each of said risk categories(RCAT) representing a range of values for LBGI; and
 - assigning said LBGI to at least one of said risk categories(RCAT).
43. (withdrawn) The method of claim 42, wherein said risk categories(RCAT) are defined as follows:
 - category 1, wherein said LBGI is less than about 0.25;
 - category 2, wherein said LBGI is between about 0.25 and about 0.50;
 - category 3, wherein said LBGI is between about 0.50 and about 0.75;
 - category 4, wherein said LBGI is between about 0.75 and about 1.0;
 - category 5, wherein said LBGI is between about 1.0 and about 1.25;

- category 6, wherein said LBGI is between about 1.25 and about 1.50;
- category 7, wherein said LBGI is between about 1.5 and about 1.75;
- category 8, wherein said LBGI is between about 1.75 and about 2.0;
- category 9, wherein said LBGI is between about 2.0 and about 2.5;
- category 10, wherein said LBGI is between about 2.5 and about 3.0
- category 11, wherein said LBGI is between about 3.0 and about 3.5;
- category 12, wherein said LBGI is between about 3.5 and about 4.25;
- category 13, wherein said LBGI is between about 4.25 and about 5.0;
- category 14, wherein said LBGI is between about 5.0 and about 6.5; and
- category 15, wherein said LBGI is above about 6.5.
44. (withdrawn) The method of claim 42, further comprising:
- defining a probability of incurring a select number of SH episodes respectively for each of said assigned risk categories(RCAT).
45. (withdrawn) The method of claim 42, further comprising:
- defining a probability of incurring a select number of SH episodes within a next first predetermined

duration respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - \exp(-a \cdot x^b)$ for any $x > 0$ and 0 otherwise,

wherein:

a = about -4.19,

b = about 1.75.

46. (withdrawn) The method of claim 45, wherein said first predetermined duration is about one month.

47. (withdrawn) The method of claim 45, wherein said first predetermined duration ranges from about 0.5 months to about 1.5 months.

48. (withdrawn) The method of claim 45, wherein said first predetermined duration ranges from about 0.5 months to about 3 months.

49. (withdrawn) The method of claim 42, further comprising:

defining a probability of incurring a select number of SH episodes within a next second predetermined duration respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - \exp(-a \cdot x^b)$ for any $x > 0$ and 0 otherwise,

wherein:

a = about -3.28,

b = about 1.50.

50. (withdrawn) The method of claim 49, wherein said second predetermined duration is about three months.

51. (withdrawn) The method of claim 49, wherein said second predetermined duration ranges from about 2

months to about 4 months.

52. (withdrawn) The method of claim 49, wherein said second predetermined duration ranges from about 3 months to about 6 months.
53. (withdrawn) The method of claim 42, further comprising:
- defining a probability of incurring a select number of SH episodes within the next third predetermined duration respectively for each of said assigned risk categories(RCAT), using the formula:
- $$F(x) = 1 - \exp(-a \cdot x^b) \text{ for any } x > 0 \text{ and } 0 \text{ otherwise,}$$
- wherein:
- a = about -3.06,
- b = about 1.45.
54. (withdrawn) The method of claim 53, wherein said third predetermined duration is about 6 months.
55. (withdrawn) The method of claim 53, wherein said third predetermined duration ranges from about 5 months to about 7 months.
56. (withdrawn) The method of claim 53, wherein said third predetermined duration ranges from about 3 months to about 9 months.
57. (withdrawn) The method of claim 42, further comprising:
- defining a probability of incurring a select number of MH episodes within the next month respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - \exp(-a \cdot x^b)$ for any $x > 0$ and 0 otherwise,
wherein:

a = about -1.58,

b = about 1.05.

58. (withdrawn) The method of claim 42, further comprising:

defining a probability of incurring a select number of MH episodes within the next 3 months respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - \exp(-a \cdot x^b)$ for any $x > 0$ and 0 otherwise,
wherein:

a = about -1.37,

b = about 1.14.

59. (withdrawn) The method of claim 42, further comprising:

defining a probability of incurring a select number of MH episodes within the next 6 months respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - \exp(-a \cdot x^b)$ for any $x > 0$ and 0 otherwise,
wherein:

a = about -1.37,

b = about 1.35.

60. (withdrawn) The method of claim 40, further comprising:

assigning classifications of risk for future

significant hypoglycemia of the patient.

61. (withdrawn) The method of claim 60, wherein said classifications are defined as follows:
- minimal risk, wherein said LBG1 is less than about 1.25;
- low risk, wherein said LBG1 is between about 1.25 and about 2.50;
- moderate risk, wherein said LBG1 is between about 2.5 and about 5; and
- high risk, wherein said LBG1 is above about 5.0.
62. (withdrawn) A system for evaluating the long term probability for severe hypoglycemia (SH) and/or moderate hypoglycemia (MH) of a patient based on BG data collected over a predetermined duration, said system comprising:
- a database component operative to maintain a database identifying said BG data; and
- a processor programmed to:
- compute LBG1 based on said collected BG data, and
- estimate the number of future SH episodes using a predetermined mathematical formula based on said computed LBG1.
63. (withdrawn) The method of claim 62, wherein:
- said computed LBG1 is mathematically defined from a series of BG readings x_1, x_2, \dots, x_n taken at time points t_1, t_2, \dots, t_n as:

$$LBG1 = \frac{1}{n} \sum_{i=1}^n lbg1(x_i; 2)$$

where:

$$lbgi(BG;a) = 10 \cdot f(BG)^a \quad \text{if } f(BG) > 0 \text{ and } 0$$

otherwise,

a = about 2, representing a weighting parameter.

64. (withdrawn) The system of claim 62, further comprising:

defining predetermined risk categories(RCAT), each of said risk categories(RCAT) representing a range of values for LBGI; and

assigning said LBGI to at least one of said risk categories(RCAT).

65. (withdrawn) The system of claim 64, wherein said risk categories (RCAT) are defined as follows:

category 1, wherein said LBGI is less than about 0.25;

category 2, wherein said LBGI is between about 0.25 and about 0.50;

category 3, wherein said LBGI is between about 0.50 and about 0.75;

category 4, wherein said LBGI is between about 0.75 and about 1.0;

category 5, wherein said LBGI is between about 1.0 and about 1.25;

category 6, wherein said LBGI is between about 1.25 and about 1.50;

category 7, wherein said LBGI is between about 1.5 and about 1.75;

category 8, wherein said LBGI is between about 1.75 and about 2.0;

category 9, wherein said LBGI is between about 2.0 and about 2.5;

category 10, wherein said LBGI is between about 2.5 and about 3.0

category 11, wherein said LBGI is between about 3.0 and about 3.5;

category 12, wherein said LBGI is between about 3.5 and about 4.25;

category 13, wherein said LBGI is between about 4.25 and about 5.0;

category 14, wherein said LBGI is between about 5.0 and about 6.5; and

category 15, wherein said LBGI is above about 6.5.

66. (withdrawn) The system of claim 64, further comprising:

defining a probability of incurring a select number of SH episodes respectively for each of said assigned risk categories (RCAT).

67. (withdrawn) The system of claim 64, further comprising:

defining a probability of incurring a select number of SH episodes within a next first predetermined duration respectively for each of said assigned risk categories (RCAT), using the formula:

$F(x) = 1 - \exp(-a \cdot x^b)$ for any $x > 0$ and 0 otherwise,
wherein:

a = about -4.19,

b = about 1.75.

68. (withdrawn) The system of claim 67, wherein said first predetermined duration is about one month.

69. (withdrawn) The system of claim 67, wherein said first predetermined duration ranges from about 0.5 months to about 1.5 months.

70. (withdrawn) The system of claim 67, wherein said first predetermined duration ranges from about 0.5 months to about 3 months.

71. (withdrawn) The system of claim 64, further comprising:

defining a probability of incurring a select number of SH episodes within a next second predetermined duration respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - \exp(-a \cdot x^b)$ for any $x > 0$ and 0 otherwise,
wherein:

a = about -3.28,

b = about 1.50.

72. (withdrawn) The system of claim 71, wherein said second predetermined duration is about three months.

73. (withdrawn) The system of claim 71, wherein said second predetermined duration ranges from about 2 months to about 4 months.

74. (withdrawn) The system of claim 71, wherein said

second predetermined duration ranges from about 3 months to about 6 months.

75. (withdrawn) The system of claim 64, further comprising:

defining a probability of incurring a select number of SH episodes within the next third predetermined duration respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - \exp(-a \cdot x^b)$ for any $x > 0$ and 0 otherwise, wherein:

a = about -3.06,

b = about 1.45.

76. (withdrawn) The system of claim 75, wherein said third predetermined duration is about 6 months.

77. (withdrawn) The system of claim 75, wherein said third predetermined duration ranges from about 5 months to about 7 months.

78. (withdrawn) The system of claim 75, wherein said third predetermined duration ranges from about 3 months to about 9 months.

79. (withdrawn) The system of claim 64, further comprising:

defining a probability of incurring a select number of MH episodes within the next month respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - \exp(-a \cdot x^b)$ for any $x > 0$ and 0 otherwise, wherein:

a = about -1.58,

b = about 1.05.

80. (withdrawn) The system of claim 64, further comprising:

defining a probability of incurring a select number of MH episodes within the next 3 months respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - \exp(-a \cdot x^b)$ for any $x > 0$ and 0 otherwise,
wherein:

a = about -1.37,

b = about 1.14.

81. (withdrawn) The system of claim 64, further comprising:

defining a probability of incurring a select number of MH episodes within the next 6 months respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - \exp(-a \cdot x^b)$ for any $x > 0$ and 0 otherwise,
wherein:

a = about -1.37,

b = about 1.35.

82. (withdrawn) The system of claim 62, further comprising:

assigning classifications of risk for future significant hypoglycemia of the patient.

83. (withdrawn) The system of claim 82, wherein said

classifications are defined as follows:

minimal risk, wherein said LBGI is less than about 1.25;

low risk, wherein said LBGI is between about 1.25 and about 2.50;

moderate risk, wherein said LBGI is between about 2.5 and about 5; and

high risk, wherein said LBGI is above about 5.0.

84. (withdrawn) A system for evaluating the long term probability for severe hypoglycemia (SH) and/or moderate hypoglycemia (MH) of a patient based on BG data collected over a predetermined duration, said system comprising:
- a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient;
 - a database component operative to maintain a database identifying said BG data; and
 - a processor programmed to:
 - compute LBGI based on said collected BG data, and
 - estimate the number of future SH episodes using a predetermined mathematical formula based on said computed LBGI.
85. (withdrawn) A computer program product comprising a computer useable medium having computer program logic for enabling at least one processor in a computer system to evaluate the long term probability for severe hypoglycemia (SH) and/or moderate hypoglycemia (MH) of a patient based on BG data collected over a

predetermined duration, said computer program logic comprising:

computing LBGI based on said collected BG data; and
estimating the number of future SH episodes using a
predetermined mathematical formula based on said
computed LBGI.

86. (withdrawn) The computer program product of claim 85, wherein said computer program logic further comprises the steps of claim 42.

87. (withdrawn) A method for evaluating the short term probability for severe hypoglycemia (SH) of a patient based on BG data collected over a predetermined duration, said method comprising:

computing scale values based on said collected BG data; and

computing the low BG risk value (RLO) for each BG data.

88. (withdrawn) The method of claim 87, wherein:

said computed RLO(BG) is mathematically defined as:

Scale = $[\ln(\text{BG})]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl

Risk = $22.765(\text{Scale})^2$

if (BG is less than about 112.5) then:

RLO(BG) = Risk, otherwise

RLO(BG) = 0.

89. (withdrawn) The method of claim 87, wherein:

said computed RLO(BG) is mathematically defined as:

Scale=[ln(BG)]^{1.026} -1.861, wherein BG is measured in units of mmol/l

$$\text{Risk} = 32.184(\text{Scale})^2$$

if (BG is \leq about 112.5) then:

RLO(BG) = Risk, otherwise

RLO(BG) = 0.

90. (withdrawn) The method of claim 87, wherein:

computing LBGI based on said collected BG data, said computed LBGI is mathematically defined from a series of BG readings x_1, x_2, \dots, x_n taken at time points t_1, t_2, \dots, t_n as:

$$LBGI = \frac{1}{n} \sum_{i=1}^n lbgi(x_i; 2)$$

where:

$$lbgi(BG; a) = RLO(BG).$$

91. (withdrawn) The method of claim 87, wherein:

computing provisional LBGI based on said collected BG data, said computed provisional LBGI is mathematically defined from mathematically defined as:

$$LBGI(1) = RLO(x_1)$$

$$RLO2(1) = 0$$

$$LBGI(j) = ((j-1)/j) * LBGI(j-1) + (1/j) * RLO(x_j)$$

$$RLO2(j) = ((j-1)/j) * RLO2(j-1) + (1/j) * (RLO(x_j) - LBGI(j))^2.$$

92. (withdrawn) The method of claim 91, wherein:

computing SBGI, said computed SBGI is mathematically defined as:

$$SBGI(n) = \sqrt{(RLO2(n))}.$$

93. (withdrawn) The method of claim 92, comprising qualifying or providing a warning of upcoming short term SH wherein if:

(LBGI(150) \geq 2.5 and LBGI(50) \geq (1.5*LBGI(150) and SBGI(50) \geq SBGI(150)) then said issue of warning is qualified or provided, or

RLO \geq (LBGI(150)+1.5*SBGI(150)) then said issue of warning is qualified or provided;

otherwise:

a warning is not necessarily qualified or provided.

94. (withdrawn) The method of claim 92, comprising qualifying or providing a warning of upcoming short term SH wherein if:

(LBGI(n) $\geq \alpha$ and SBGI(n) $\geq \beta$) then said issue of warning is qualified or provided, and/or

(RLO(n) \geq (LBGI(n) + γ * SBGI(n))) then said issue of warning is qualified or provided;

otherwise:

a warning is not necessarily qualified or provided, wherein α , β , and γ are threshold parameters.

95. (withdrawn) The method of claim 94, wherein said threshold parameters α , β , and γ are defined as α = about 5, β = about 7.5, γ = about 1.5.

96. (withdrawn) The method of claim 94, wherein said threshold parameters α , β , and γ are defined as any combination in a, b, and/or c, or as any intermediate

combination of values of said parameters between the values of said parameters in a, b, and/or c below:

- a) $\alpha = 6.4$, $\beta = 8.2$, $\gamma = 1.5$, $\alpha = 5.0$, $\beta = 7.5$, $\gamma = 1.3$;
- b) $\alpha = 6.0$, $\beta = 7.5$, $\gamma = 1.5$, $\alpha = 4.9$, $\beta = 7.0$, $\gamma = 1.2$; and/or
- c) $\alpha = 5.5$, $\beta = 7.5$, $\gamma = 1.5$, $\alpha = 4.8$, $\beta = 7.0$, $\gamma = 1.2$.

97. (withdrawn) The method of claim 94, wherein said threshold parameters α , β , and γ are defined as any combination in a, b, and/or c, or as any intermediate combination of values of said parameters between the values of said parameters in a, b, and/or c below:

- a). α about 6.4, β about 8.2, γ about 1.5, α about 5.0, β about 7.5, γ about 1.3;
- b). α about 6.0, β about 7.5, γ about 1.5, α about 4.9, β about 7.0, γ about 1.2; and/or
- c). α about 5.5, β about 7.5, γ about 1.5, α about 4.8, β about 7.0, γ about 1.2.

98. (withdrawn) A system for evaluating the short term probability for severe hypoglycemia (SH) of a patient based on BG data collected over a predetermined duration, said system comprising:

- a database component operative to maintain a database identifying said BG data; and
- a processor programmed to:
 - compute scale values based on said collected BG data;

and

compute the low BG risk value (RLO) for each BG data.

99. (withdrawn) The system of claim 98, wherein:

said computed RLO(BG) is mathematically defined as:

Scale = $[\ln(\text{BG})]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl

Risk = $22.765(\text{Scale})^2$

if (BG is less than about 112.5) then:

RLO(BG) = Risk, otherwise

RLO(BG) = 0.

100. (withdrawn) The system of claim 98, wherein:

said computed RLO(BG) is mathematically defined as:

Scale = $[\ln(\text{BG})]^{1.026} - 1.861$, wherein BG is measured in units of mmol/l

Risk = $32.184(\text{Scale})^2$

if (BG is \leq about 112.5) then:

RLO(BG) = Risk, otherwise

RLO(BG) = 0.

101. (withdrawn) The system of claim 98, wherein:

computing LBGi based on said collected BG data, said computed LBGi is mathematically defined from a series of BG readings x_1, x_2, \dots, x_n taken at time points t_1, t_2, \dots, t_n as:

$$LBGI = \frac{1}{n} \sum_{i=1}^n lbgi(x_i; 2)$$

where:

$$lbg_i(BG;a) = RLO(BG).$$

102. (withdrawn) The system of claim 98, wherein:

computing provisional LBGI based on said collected BG data, said computed provisional LBGI is mathematically defined from mathematically defined as:

$$LBGI(1) = RLO(x_1)$$

$$RLO2(1) = 0$$

$$LBGI(j) = ((j-1)/j) * LBGI(j-1) + (1/j) * RLO(x_j)$$

$$RLO2(j) = ((j-1)/j) * RLO2(j-1) + (1/j) * (RLO(x_j) - LBGI(j))^2.$$

103. (withdrawn) The system of claim 102, wherein:

computing SBGI, said computed SBGI is mathematically defined as:

$$SBGI(n) = \sqrt{(RLO2(n))}.$$

104. (withdrawn) The system of claim 103, comprising qualifying or providing a warning of upcoming short term SH wherein if:

$(LBGI(150) \geq 2.5$ and $LBGI(50) \geq (1.5 * LBGI(150))$ and $SBGI(50) \geq SBGI(150))$ then said issue of warning is qualified or provided, or

$RLO \geq (LBGI(150) + 1.5 * SBGI(150))$ then said issue of warning is qualified or provided;

otherwise:

a warning is not necessarily qualified or provided.

105. (withdrawn) The system of claim 103, comprising qualifying or providing a warning of upcoming short term SH wherein if:

(LBGI(n) $\geq \alpha$ and SBGI(n) $\geq \beta$) then said issue of warning is qualified or provided, and/or

(RLO(n) \geq (LBGI(n) + γ * SBGI(n))) then said issue of warning is qualified or provided;

otherwise:

a warning is not necessarily qualified or provided, wherein α , β , and γ are threshold parameters.

106. (withdrawn) The system of claim 105, wherein said threshold parameters α , β , and γ are defined as α = about 5, β = about 7.5, γ = about 1.5.

107. (withdrawn) The system of claim 105, wherein said threshold parameters α , β , and γ are defined as any combination in a, b, and/or c, or as any intermediate combination of values of said parameters between the values of said parameters in a, b, and/or c below:

a) $\alpha = 6.4$, $\beta = 8.2$, $\gamma = 1.5$, $\alpha = 5.0$, $\beta = 7.5$, $\gamma = 1.3$;

b) $\alpha = 6.0$, $\beta = 7.5$, $\gamma = 1.5$, $\alpha = 4.9$, $\beta = 7.0$, $\gamma = 1.2$; and/or

c) $\alpha = 5.5$, $\beta = 7.5$, $\gamma = 1.5$, $\alpha = 4.8$, $\beta = 7.0$, $\gamma = 1.2$.

108. (withdrawn) The system of claim 105, wherein said threshold parameters α , β , and γ are defined as any combination in a, b, and/or c, or as any intermediate combination of values of said parameters between the values of said parameters in a, b, and/or c below:

a). α about 6.4, β about 8.2, γ about 1.5, α about

- 5.0, β about 7.5, γ about 1.3;
- b). α about 6.0, β about 7.5, γ about 1.5, α about 4.9, β about 7.0, γ about 1.2; and/or
- c). α about 5.5, β about 7.5, γ about 1.5, α about 48, β about 7.0, γ about 1.2.
109. (withdrawn) A system for evaluating the short term probability for severe hypoglycemia (SH) of a patient based on BG data collected over a predetermined duration, said system comprising:
- a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient;
 - a database component operative to maintain a database identifying said BG data; and
 - a processor programmed to:
 - compute scale values based on said collected BG data; and
 - compute the low BG risk value (RLO) for each BG data.
110. (withdrawn) A computer program product comprising a computer useable medium having computer program logic for enabling at least one processor in a computer system to evaluating the short term probability for severe hypoglycemia (SH) of a patient based on BG data collected over a predetermined duration, said computer program logic comprising:
- computing scale values based on said collected BG data; and
 - computing the low BG risk value (RLO) for each BG data.

111. (withdrawn) The computer program product of claim 110, wherein said computer program logic further comprises the steps of claim 92.
112. (currently amended) The method of claim 11, wherein the validation of the HbA_{1c} estimate using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:
- a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and
 - b) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1) \geq about 0.005),
wherein
RLO1 is the Low BG Index of claim 6
RHI1 is the High BG Index of claim 6; or
 - c) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 \geq about 3%),
wherein
NO6 is the percentage of readings during the night of claim 6.
113. (original) The method of claim 112, wherein said third predetermined duration is at least about 35 days.
114. (currently amended) The system of claim 29, wherein the validation of the HbA_{1c} estimate using sample selection criteria of HbA_{1c} estimate only if the

first predetermined duration sample meets at least one of the following four criteria:

- a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and
- b) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio $(RL01/RHI1) \geq$ about 0.005),

wherein

RL01 is the Low BG Index of claim 24

RHI1 is the High BG Index of claim 24; or

- c) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio $(NO6 \geq$ about 3%),

wherein

NO6 is the percentage of readings during the night of claim 24.

115. (original) The system of claim 114, wherein said third predetermined duration is at least about 35 days.

116. (previously presented) The system of claim 37, wherein said first predetermined duration is about 60 days.

117. (previously presented) The system of claim 37, wherein said first predetermined duration ranges from about 45 days to about 75 days.

118. (previously presented) The system of claim 37, wherein said first predetermined duration ranges from about 45 days to about 90 days.

119. (currently amended) The system of claim 37, wherein

the pre-processing of the data ~~for each patient~~
comprises:

conversion of plasma data to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l;
and

computing Low Blood Glucose Index (RL01) and High
Blood Glucose Index (RHI1).

120. (currently amended) The system of claim 37, wherein
the preprocessing of the data ~~for each patient using
predetermined mathematical formulas is defined as
comprises:~~

conversion of plasma data to whole blood BG mg/dl via
 $BG = PLASBG \text{ (mg/dl)} / 1.12$;

conversion of BG measured in mg/dl to units of mmol/l)
via $BGMM = BG / 18$; and

computing Low Blood Glucose Index (RL01) and High
Blood Glucose Index (RHI1) using a predetermined
mathematical formula defined as:

$Scale = [\ln(BG)]^{1.0845} - 5.381$, wherein BG is
measured in units of mg/dl,

$Risk1 = 22.765(Scale)^2$, wherein

$RiskLO = Risk1$ if (BG is less than about 112.5) and
therefore risk of LBGI exists, otherwise
 $RiskLO = 0$, and

$RiskHI = Risk1$ if (BG is greater than about 112.5)
and therefore risk of HBGI exists, otherwise
 $RiskHI = 0$,

$BGMM1 = \text{average of BGMM per patient,}$

RL01 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

121. (previously presented) The system of claim 120, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.
122. (previously presented) The system of claim 120, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:
- if (RHI1 is \leq about 5.25 or if RHI1 is \geq about 16)
then the assigned group= 0,
 - if (RHI1 is $>$ about 5.25 and if RHI1 is $<$ about 7.0) then the assigned group=1,
 - if (RHI1 is \geq about 7.0 and if RHI1 is $<$ about 8.5) then the assign group=2, and
 - if (RHI1 is \geq about 8.5 and if RHI1 is $<$ about 16)
then the assigned group=3.

123. (previously presented) The system of claim 122, comprising providing estimates using a predetermined mathematical formula defined as:

$$E0 = 0.55555 * BGMM1 + 2.95,$$

$$E1 = 0.50567 * BGMM1 + 0.074 * L06 + 2.69,$$

$$E2 = 0.55555 * BGMM1 - 0.074 * L06 + 2.96,$$

$$E3 = 0.44000 * BGMM1 + 0.035 * L06 + 3.65; \text{ and}$$

if (Group = 1) then EST2=E1, or if (Group = 2) then EST2=E2, or if (Group = 3) then EST2=E3, otherwise EST2=E0.

124. (previously presented) The system of claim 123, comprising providing further correction of the estimates using a predetermined mathematical formula defined as:

if (missing(L06)) EST2=E0,

if (RL01 is \leq about 0.5 and RH11 is \leq about 2.0) then EST2=E0-0.25,

if (RL01 is \leq about 2.5 and RH11 is $>$ about 26) then EST2=E0-1.5*RL01, and

if ((RL01/RH11) is \leq about 0.25 and L06 is $>$ about 1.3) then EST2=EST2-0.08.

125. (currently amended) The system of claim 124 for estimating the HbA_{1c} of a patient based on BG data collected over the first predetermined duration, said system comprising:

said estimating HbA_{1c} using said at least one of four predetermined mathematical formulas defined as:

- a) $HbA_{1c} = \frac{1}{10} \times \text{the EST2 defined by claim 8 or as}$

corrected by claim 10 or

b) $HbA_{1c} = 0.809098 * BGMM1 + 0.064540 * RLO1 - 0.151673 * RHI1 + 1.873325$, wherein

BGMM1 is the average BG (mmol/l) of claim 120,

RLO1 is the Low BG Index of claim 120,

RHI1 is the High BG Index of claim 120; or

c) $HbA_{1c} = 0.682742 * HBA0 + 0.054377 * RHI1 + 1.553277$, wherein

HBA0 is a previous reference HbA_{1c} reading taken about a second predetermined period prior to the estimate, wherein

RHI1 = is the High BG Index of claim 120; or

d) $HbA_{1c} = 0.41046 * BGMM1 + 4.0775$

wherein BGMM1 is the average BG (mmol/l) of claim 120.

126. (previously presented) The system of claim 125, wherein said second predetermined duration is about three months.
127. (previously presented) The system of claim 125, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.
128. (previously presented) The system of claim 125, wherein said second predetermined duration ranges from about 2.5 months to six months.
129. (currently amended) The system of claim 125, wherein the validation of the HbA_{1c} estimate using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

- a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;
 - b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;
 - c) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio $(RLO1/RHI1) \geq$ about 0.005),
wherein
RLO1 is the Low BG Index of claim 120,
RHI1 is the High BG Index of claim 120; or
 - d) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio $(N06 \geq$ about 3%),
wherein
N06 is the percentage of readings during the night of claim 120.
130. (previously presented) The system of claim 129, wherein said third predetermined duration is at least 35 days.
131. (previously presented) The system of claim 129, wherein said third predetermined duration ranges from about 35 days to about 40 days.
132. (previously presented) The system of claim 129, wherein said third predetermined duration ranges from

about 35 days to about as long as the first predetermined duration.

133. (currently amended) The system of claim 125, wherein the validation of the HbA_{1c} estimate using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

- a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and
- b) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio $(RLO1/RHI1) \geq$ about 0.005),

wherein

RLO1 is the Low BG Index of claim 120

RHI1 is the High BG Index of claim 120; or

- c) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio $(NO6 \geq$ about 3%),

wherein

NO6 is the percentage of readings during the night of claim 120.

134. (previously presented) The system of claim 133, wherein said third predetermined duration is at least about 35 days.

135. (currently amended) A method for evaluating the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said

method comprising:

~~preparing the data for estimating HbA_{1c} using a
predetermined sequence of mathematical formulas
defined as:~~

pre-processing [[of]] the collected BG data to
convert the collected BG data into derived BG
data derived from said collected BG data,
validation of a sample of the collected BG data
via sample selection criteria, [[and]]
estimating HbA_{1c} from said derived BG data if the
sample is valid,[[;]]
electronically transforming the estimate into a
visual depiction, and
outputting the visual depiction of the estimate
to a user.

136. (previously presented) The method of claim 135,
wherein said first predetermined duration is about 60
days.
137. (previously presented) The method of claim 135,
wherein said first predetermined duration ranges from
about 45 days to about 75 days.
138. (previously presented) The method of claim 135,
wherein said first predetermined duration ranges from
about 45 days to about 90 days.
139. (currently amended) The method of claim 135, wherein
the preprocessing of the data ~~for each patient~~
comprises:
conversion of plasma to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l;
and

computing Low Blood Glucose Index (RLO1) and High
Blood Glucose Index (RHI1).

140. (currently amended) The method of claim 135, wherein
the preprocessing of the data ~~for each patient using
predetermined mathematical formulas is defined as~~
comprises:

conversion of plasma to whole blood BG mg/dl via
 $BG = PLASBG \text{ (mg/dl)} / 1.12$;

conversion of BG measured in mg/dl to units of mmol/l
via $BGMM = BG / 18$; and

computing Low Blood Glucose Index (RLO1) and High
Blood Glucose Index (RHI1) using a predetermined
mathematical formula defined as:

$Scale = [\ln(BG)]^{1.0845} - 5.381$, wherein BG is
measured in units of mg/dl,

$Risk1 = 22.765(Scale)^2$, wherein

$RiskLO = Risk1$ if (BG is less than about 112.5) and
therefore risk of LBGI exists, otherwise
 $RiskLO = 0$, and

$RiskHI = Risk1$ if (BG is greater than about 112.5)
and therefore risk of HBGI exists, otherwise
 $RiskHI = 0$,

$BGMM1$ = average of BGMM per patient,

$RLO1$ = average of RiskLO per patient,

$RHI1$ = average of RiskHI per patient,

$L06$ = average of RiskLO computed only for

readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

141. (previously presented) The method of claim 140, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.
142. (previously presented) The method of claim 140, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:
- if (RHI1 is \leq about 5.25 or if RHI1 is \geq about 16) then the assigned group= 0,
- if (RHI1 is $>$ about 5.25 and if RHI1 is $<$ about 7.0) then the assigned group=1,
- if (RHI1 is \geq about 7.0 and if RHI1 is $<$ about 8.5) then the assign group=2, and
- if (RHI1 is \geq about 8.5 and if RHI1 is $<$ about 16) then the assigned group=3.
143. (previously presented) The method of claim 142, comprising providing estimates using a predetermined mathematical formula defined as:

$E0 = 0.55555 * BGMM1 + 2.95,$
 $E1 = 0.50567 * BGMM1 + 0.074 * L06 + 2.69,$
 $E2 = 0.55555 * BGMM1 - 0.074 * L06 + 2.96,$
 $E3 = 0.44000 * BGMM1 + 0.035 * L06 + 3.65;$ and
 if (Group = 1) then $EST2 = E1$, or if (Group = 2) then
 $EST2 = E2$, or if (Group = 3) then $EST2 = E3$, otherwise
 $EST2 = E0$.

144. (previously presented) The method of claim 143, comprising providing further correction of the estimates using a predetermined mathematical formula defined as:

if (missing(L06)) $EST2 = E0$,
 if (RLO1 is \leq about 0.5 and RHI1 is \leq about 2.0) then
 $EST2 = E0 - 0.25$,
 if (RLO1 is \leq about 2.5 and RHI1 is $>$ about 26) then
 $EST2 = E0 - 1.5 * RLO1$, and
 if ((RLO1/RHI1) is \leq about 0.25 and L06 is $>$ about 1.3)
 then $EST2 = EST2 - 0.08$.

145. (currently amended) The method of claim 144 for estimating the HbA_{1c} of a patient based on BG data collected over the first predetermined duration, said method comprising:

estimating HbA_{1c} using at least one of four predetermined mathematical formulas defined as:

- a) $HbA_{1c} = \frac{EST2}{1.4}$ = the $EST2$ defined by claim 8 or as corrected by claim 10 or
 b) $HbA_{1c} = 0.809098 * BGMM1 + 0.064540 * RLO1 - 0.151673 * RHI1 + 1.873325$, wherein

BGMM1 is the average BG (mmol/l) of claim 140.

RLO1 is the Low BG Index of claim 140.

RHI1 is the High BG Index of claim 140; or

- c) $HbA_{1c} = 0.682742 * HBA0 + 0.054377 * RHI1 + 1.553277$, wherein

HBA0 is a previous reference HbA_{1c} reading taken about a second predetermined period prior to the estimate, wherein

RHI1 = is the High BG Index of claim 140; or

- d) $HbA_{1c} = 0.41046 * BGMM + 4.0775$

wherein BGMM1 is the average BG (mmol/l) of claim 140.

146. (previously presented) The method of claim 145, wherein said second predetermined duration is about three months.
147. (previously presented) The method of claim 145, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.
148. (previously presented) The method of claim 145, wherein said second predetermined duration ranges from about 2.5 months to six months.
149. (currently amended) The method of claim 145, wherein the validation of the sample using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:
- a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;

- b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;
 - c) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio $(RL01/RH11) \geq$ about 0.005),
wherein
RL01 is the Low BG Index of claim 140
RH11 is the High BG Index of claim 140; or
 - d) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio $(N06 \geq$ about 3%).
wherein
N06 is the percentage of readings during the night of claim 140.
150. (previously presented) The method of claim 149, wherein said third predetermined duration is at least 35 days.
151. (previously presented) The method of claim 149, wherein said third predetermined duration ranges from about 35 days to about 40 days.
152. (previously presented) The method of claim 149, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.
153. (currently amended) The method of claim 145, wherein

the validation of the sample using sample selection criteria of HbA_{1c} ~~1c~~ estimate only if the first predetermined duration sample meets at least one of the following four criteria:

- a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and
- b) a randomness of data criterion-1 wherein the HbA_{1c} ~~1c~~ estimate is validated or displayed only if the ratio $(RL01/RHI1) \geq$ about 0.005),

wherein

RL01 is the Low BG Index of claim 149

RHI1 is the High BG Index of claim 140; or

- c) a randomness of data criterion-2 wherein HbA_{1c} ~~1c~~ estimate is validated or displayed only if the ratio $(N06 \geq$ about 3%),

wherein

N06 is the percentage of readings during the night of claim 140.

154. (previously presented) The method of claim 153, wherein said third predetermined duration is at least about 35 days.

155. (currently amended) A system for evaluating the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

~~prepare the data for estimating HbA_{1c} using a
predetermined sequence of mathematical formulas
defined as:~~

pre-process the collected BG data to convert
the collected BG data into derived BG data
derived from said collected BG data,

validate a sample of the collected BG data
via sample selection criteria, and

estimate HbA_{1c} from said derived BG data if
the sample is valid; and

output the estimate to a user.

156. (previously presented) The system of claim 155,
wherein said first predetermined duration is about 60
days.

157. (previously presented) The system of claim 155,
wherein said first predetermined duration ranges from
about 45 days to about 75 days.

158. (previously presented) The system of claim 155,
wherein said first predetermined duration ranges from
about 45 days to about 90 days.

159. (currently amended) The system of claim 155, wherein
the preprocessing of the data ~~for each patient~~
comprises:

conversion of plasma to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l;
and

computing Low Blood Glucose Index (RL01) and High

Blood Glucose Index (RHI1).

160. (currently amended) The system of claim 155, wherein the preprocessing of the data ~~for each patient using predetermined mathematical formulas is defined as~~ comprises:

conversion of plasma to whole blood BG mg/dl via $BG = PLASBG \text{ (mg/dl)} / 1.12$;

conversion of BG measured in mg/dl to units of mmol/l via $BGMM = BG / 18$; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

$Scale = [\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

$Risk1 = 22.765(Scale)^2$, wherein

$RiskLO = Risk1$ if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise $RiskLO = 0$, and

$RiskHI = Risk1$ if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise $RiskHI = 0$,

$BGMM1$ = average of BGMM per patient,

$RLO1$ = average of RiskLO per patient,

$RHI1$ = average of RiskHI per patient,

$L06$ = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

$N06$, $N12$, $N24$ are percentage of SMBG readings in time intervals,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

161. (previously presented) The system of claim 160, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.
162. (previously presented) The system of claim 160, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:
- if (RHI1 is \leq about 5.25 or if RHI1 is \geq about 16) then the assigned group= 0,
- if (RHI1 is $>$ about 5.25 and if RHI1 is $<$ about 7.0) then the assigned group=1,
- if (RHI1 is \geq about 7.0 and if RHI1 is $<$ about 8.5) then the assign group=2, and
- if (RHI1 is \geq about 8.5 and if RHI1 is $<$ about 16) then the assigned group=3.
163. (previously presented) The system of claim 162, comprising providing estimates using a predetermined mathematical formula defined as:
- $E0 = 0.55555 * BGMM1 + 2.95,$
- $E1 = 0.50567 * BGMM1 + 0.074 * L06 + 2.69,$
- $E2 = 0.55555 * BGMM1 - 0.074 * L06 + 2.96,$
- $E3 = 0.44000 * BGMM1 + 0.035 * L06 + 3.65;$ and

if (Group = 1) then $EST2=E1$, or if (Group = 2) then $EST2=E2$, or if (Group = 3) then $EST2=E3$, otherwise $EST2=E0$.

164. (previously presented) The system of claim 163, comprising providing further correction of the estimates using a predetermined mathematical formula defined as:

if (missing(L06)) $EST2=E0$,
 if (RLO1 is \leq about 0.5 and RHI1 is \leq about 2.0) then $EST2=E0-0.25$,
 if (RLO1 is \leq about 2.5 and RHI1 is $>$ about 26) then $EST2=E0-1.5*RLO1$, and
 if ((RLO1/RHI1) is \leq about 0.25 and L06 is $>$ about 1.3) then $EST2=EST2-0.08$.

165. (currently amended) The system of claim 164 for estimating the HbA_{1c} of a patient based on BG data collected over the first predetermined duration, said system comprising:

estimating HbA_{1c} using at least one of four predetermined mathematical formulas defined as:

- a) $HbA_{1c} = \text{the } EST2 \text{ defined by claim 8 or as corrected by claim 10 or}$
 b) $HbA_{1c} = 0.809098*BGMM1 + 0.064540*RLO1 - 0.151673*RHI1 + 1.873325$, wherein
 $BGMM1$ is the average BG (mmol/l) of claim 160,
 $RLO1$ is the Low BG Index of claim 160,
 $RHI1$ is the High BG Index of claim 160; or
 c) $HbA_{1c} = 0.682742*HBA0 + 0.054377*RHI1 +$

1.553277, wherein

HBA0 is a previous reference HbA_{1c} reading taken about a second predetermined period prior to the estimate, wherein

RHI1 = is the High BG Index of claim 160; or

d) $HbA_{1c} = 0.41046 * BGMM + 4.0775$

wherein BGMM1 is the average BG (mmol/l) of claim 160.

166. (previously presented) The system of claim 165, wherein said second predetermined duration is about three months.
167. (previously presented) The system of claim 165, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.
168. (previously presented) The system of claim 165, wherein said second predetermined duration ranges from about 2.5 months to six months.
169. (currently amended) The system of claim 165, wherein the validation of the sample using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:
- a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;
 - b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;

- c) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio $(RLO1/RHI1) \geq$ about 0.005),
wherein
RLO1 is the Low BG Index of claim 160,
RHI1 is the High BG Index of claim 160; or
- d) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio $(N06 \geq$ about 3%),
wherein
N06 is the percentage of readings during the night of claim 160.
170. (previously presented) The system of claim 169,
wherein said third predetermined duration is at least 35 days.
171. (previously presented) The system of claim 169,
wherein said third predetermined duration ranges from about 35 days to about 40 days.
172. (previously presented) The system of claim 169,
wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.
173. (currently amended) The system of claim 165, wherein the validation of the sample using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

- a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and
 - b) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio $(RLO1/RHI1) \geq$ about 0.005),
wherein
RLO1 is the Low BG Index of claim 160
RHI1 is the High BG Index of claim 160; or
 - c) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio $(NO6 \geq$ about 3%),
wherein
NO6 is the percentage of readings during the night of claim 160.
174. (previously presented) The system of claim 173, wherein said third predetermined duration is at least about 35 days.
175. (currently amended) A system for evaluating the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:
- a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient;
 - a database component operative to maintain a database identifying said BG data; and
 - a processor programmed to:

~~prepare the data for estimating HbA_{1c} using a~~

~~predetermined sequence of mathematical formulae
defined as:~~

pre-process the acquired BG data to convert
the acquired BG data into derived BG data
derived from said acquired BG data;

validate a sample of the acquired BG data
via sample selection criteria; [[and]]

estimate HbA_{1c} from said derived BG data if
the sample is valid; and

output the HbA_{1c} estimate to a user.

176. (previously presented) The system of claim 175,
wherein said first predetermined duration is about 60
days.
177. (previously presented) The system of claim 175,
wherein said first predetermined duration ranges from
about 45 days to about 75 days.
178. (previously presented) The system of claim 175,
wherein said first predetermined duration ranges from
about 45 days to about 90 days.
179. (currently amended) The system of claim 175, wherein
the preprocessing of the data ~~for each patient~~
comprises:
conversion of plasma to whole blood BG mg/dl;
conversion of BG measured in mg/dl to units of mmol/l;
and
computing Low Blood Glucose Index (RL01) and High
Blood Glucose Index (RHI1).
180. (currently amended) The system of claim 175, wherein

the pre-processing of the data ~~for each patient using predetermined mathematical formulas is defined~~
as comprises:

conversion of plasma to whole blood BG mg/dl via
 $BG = PLASBG \text{ (mg/dl)} / 1.12;$

conversion of BG measured in mg/dl to units of mmol/l)
via $BGMM = BG / 18;$ and

computing Low Blood Glucose Index (RLO1) and High
Blood Glucose Index (RHI1) using a predetermined
mathematical formula defined as:

$Scale = [\ln(BG)]^{1.0845} - 5.381,$ wherein BG is
measured in units of mg/dl,

$Risk1 = 22.765(Scale)^2,$ wherein

$RiskLO = Risk1$ if (BG is less than about 112.5) and
therefore risk of LBGI exists, otherwise
 $RiskLO = 0,$ and

$RiskHI = Risk1$ if (BG is greater than about 112.5)
and therefore risk of HBGI exists, otherwise
 $RiskHI = 0,$

$BGMM1 =$ average of BGMM per patient,

$RLO1 =$ average of RiskLO per patient,

$RHI1 =$ average of RiskHI per patient,

$L06 =$ average of RiskLO computed only for
readings during the night, otherwise missing if
there are no readings at night,

$N06, N12, N24$ are percentage of SMBG readings in
time intervals,

$NC1 =$ total number of SMBG readings in the first

predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

181. (previously presented) The system of claim 180, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.
182. (previously presented) The system of claim 180, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:
- if (RHI1 is \leq about 5.25 or if RHI1 is \geq about 16) then the assigned group= 0,
- if (RHI1 is $>$ about 5.25 and if RHI1 is $<$ about 7.0) then the assigned group=1,
- if (RHI1 is \geq about 7.0 and if RHI1 is $<$ about 8.5) then the assign group=2, and
- if (RHI1 is \geq about 8.5 and if RHI1 is $<$ about 16) then the assigned group=3.
183. (previously presented) The system of claim 182, comprising providing estimates using a predetermined mathematical formula defined as:
- $E0 = 0.55555 * BGMM1 + 2.95,$
- $E1 = 0.50567 * BGMM1 + 0.074 * L06 + 2.69,$
- $E2 = 0.55555 * BGMM1 - 0.074 * L06 + 2.96,$
- $E3 = 0.44000 * BGMM1 + 0.035 * L06 + 3.65;$ and
- if (Group = 1) then EST2=E1, or if (Group = 2) then

EST2=E2, or if (Group = 3) then EST2=E3, otherwise
EST2=E0.

184. (previously presented) The system of claim 183,
comprising providing further correction of the
estimates using a predetermined mathematical formula
defined as:

if (missing(L06)) EST2=E0,

if (RLO1 is \leq about 0.5 and RHI1 is \leq about 2.0) then
EST2=E0-0.25,

if (RLO1 is \leq about 2.5 and RHI1 is $>$ about 26) then
EST2=E0-1.5*RLO1, and

if ((RLO1/RHI1) is \leq about 0.25 and L06 is $>$ about 1.3)
then EST2=EST2-0.08.

185. (currently amended) The system of claim 184 for
estimating the HbA_{1c} of a patient based on BG data
collected over the first predetermined duration, said
system comprising:

estimating HbA_{1c} using at least one of four
predetermined mathematical formulas defined as:

- a) $HbA_{1c} = \text{the EST2 defined by claim 8 or as corrected by claim 10 or}$

b) $HbA_{1c} = 0.809098*BGMM1 + 0.064540*RLO1 - 0.151673*RHI1 + 1.873325$, wherein
BGMM1 is the average BG (mmol/l) of claim 180,
RLO1 is the Low BG Index of claim 180,
RHI1 is the High BG Index of claim 180; or

c) $HbA_{1c} = 0.682742*HBA0 + 0.054377*RHI1 + 1.553277$, wherein

HBA0 is a previous reference HbA_{1c} reading taken about a second predetermined period prior to the estimate, wherein

RH11 = is the High BG Index of claim 180; or

$$d) \text{ HbA}_{1c} = 0.41046 \cdot \text{BGMM} + 4.0775$$

wherein BGMM1 is the average BG (mmol/l) of claim 180.

186. (previously presented) The system of claim 185, wherein said second predetermined duration is about three months.
187. (previously presented) The system of claim 185, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.
188. (previously presented) The system of claim 185, wherein said second predetermined duration ranges from about 2.5 months to six months.
189. (currently amended) The system of claim 185, wherein the validation of the sample using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:
- a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;
 - b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;

- c) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio $(RLO1/RHI1) \geq$ about 0.005),
wherein
RLO1 is the Low BG Index of claim 180,
RHI1 is the High BG Index of claim 180; or
- d) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio $(N06 \geq$ about 3%),
wherein
N06 is the percentage of readings during the night of claim 180.
190. (previously presented) The system of claim 189,
wherein said third predetermined duration is at least 35 days.
191. (previously presented) The system of claim 189,
wherein said third predetermined duration ranges from about 35 days to about 40 days.
192. (previously presented) The system of claim 189,
wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.
193. (currently amended) The system of claim 185, wherein the validation of the sample using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

- a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and
- b) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio $(RLO1/RHI1) \geq$ about 0.005),
wherein
RLO1 is the Low BG Index of claim 180
RHI1 is the High BG Index of claim 180; or
- c) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio $(N06 \geq$ about 3%),
wherein
N06 is the percentage of readings during the night of claim 180.
194. (previously presented) The system of claim 193,
wherein said third predetermined duration is at least about 35 days.
195. (currently amended) A method for evaluating the HbA_{1c} of a patient without the need for prior HbA_{1c} information based on blood glucose (BG) data collected over a first predetermined duration, said method comprising:
~~preparing the data for estimating HbA_{1c} using a predetermined sequence of mathematical formulas defined as:~~
pre-processing [[of]] the collected BG data to convert the collected BG data into derived BG

data derived from said collected BG data,
validation of a sample of the collected BG data
via sample selection criteria, [[and]]
estimating HbA_{1c} from said derived BG data if the
sample is valid;
electronically transforming the estimate into a
visual depiction; and

outputting the estimate to a user.

196. (previously presented) The method of claim 195,
wherein said first predetermined duration is about 60
days.
197. (previously presented) The method of claim 195,
wherein said first predetermined duration ranges from
about 45 days to about 75 days.
198. (previously presented) The method of claim 195,
wherein said first predetermined duration ranges from
about 45 days to about 90 days.
199. (currently amended) The method of claim 195, wherein
the preprocessing of the data ~~for each patient~~
comprises:
conversion of plasma data to whole blood BG mg/dl;
conversion of BG measured in mg/dl to units of mmol/l;
and
computing Low Blood Glucose Index (RL01) and High
Blood Glucose Index (RHI1).
200. (currently amended) The method of claim 195, wherein
the preprocessing of the data ~~for each patient using~~
~~predetermined mathematical formulas is defined~~

comprises:

conversion of plasma to whole blood BG mg/dl via
 $BG = PLASBG \text{ (mg/dl)} / 1.12$;

conversion of BG measured in mg/dl to units of mmol/l)
via $BGMM = BG / 18$; and

computing Low Blood Glucose Index (RL01) and High
Blood Glucose Index (RHI1) using a predetermined
mathematical formula defined as:

$Scale = [\ln(BG)]^{1.0845} - 5.381$, wherein BG is
measured in units of mg/dl,

$Risk1 = 22.765(Scale)^2$, wherein

$RiskLO = Risk1$ if (BG is less than about 112.5) and
therefore risk of LBGI exists, otherwise
 $RiskLO = 0$, and

$RiskHI = Risk1$ if (BG is greater than about 112.5)
and therefore risk of HBGI exists, otherwise
 $RiskHI = 0$,

$BGMM1$ = average of BGMM per patient,

$RL01$ = average of $RiskLO$ per patient,

$RHI1$ = average of $RiskHI$ per patient,

$L06$ = average of $RiskLO$ computed only for
readings during the night, otherwise missing if
there are no readings at night,

$N06$, $N12$, $N24$ are percentage of SMBG readings in
time intervals,

NCl = total number of SMBG readings in the first
predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

201. (previously presented) The method of claim 200, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.
202. (previously presented) The method of claim 200, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:
- if (RHI1 is \leq about 5.25 or if RHI1 is \geq about 16)
then the assigned group= 0,
- if (RHI1 is $>$ about 5.25 and if RHI1 is $<$ about 7.0) then the assigned group=1,
- if (RHI1 is \geq about 7.0 and if RHI1 is $<$ about 8.5) then the assign group=2, and
- if (RHI1 is \geq about 8.5 and if RHI1 is $<$ about 16)
then the assigned group=3.
203. (previously presented) The method of claim 202, comprising providing estimates using a predetermined mathematical formula defined as:

$$E0 = 0.55555 \cdot \text{BGMM1} + 2.95,$$

$$E1 = 0.50567 \cdot \text{BGMM1} + 0.074 \cdot \text{L06} + 2.69,$$

$$E2 = 0.55555 \cdot \text{BGMM1} - 0.074 \cdot \text{L06} + 2.96,$$

$$E3 = 0.44000 \cdot \text{BGMM1} + 0.035 \cdot \text{L06} + 3.65; \text{ and}$$

if (Group = 1) then EST2=E1, or if (Group = 2)
then EST2=E2, or if (Group = 3) then EST2=E3,

otherwise $EST2=E0$.

204. (previously presented) The method of claim 203, comprising providing further correction of the estimates using a predetermined mathematical formula defined as:

if (missing(L06)) $EST2=E0$,
if (RLO1 is \leq about 0.5 and RHI1 is \leq about 2.0)
then $EST2=E0-0.25$,
if (RLO1 is \leq about 2.5 and RHI1 is $>$ about 26)
then $EST2=E0-1.5*RLO1$, and
if ((RLO1/RHI1) is \leq about 0.25 and L06 is $>$ about 1.3) then $EST2=EST2-0.08$.

205. (currently amended) The method of claim 204 for estimating the HbA_{1c} of a patient based on BG data collected over the first predetermined duration, said method comprising:

estimating HbA_{1c} using at least one of four predetermined mathematical formulas defined as:

- a) $HbA_{1c}^{le} =$ the $EST2$ defined by claim 8 or as corrected by claim 10 or
b) $HbA_{1c} = 0.809098*BGMM1 + 0.064540*RLO1 - 0.151673*RHI1 + 1.873325$, wherein
 $BGMM1$ is the average BG (mmol/l) of claim 200,
 $RLO1$ is the Low BG Index of claim 200,
 $RHI1$ is the High BG Index of claim 200; or
c) $HbA_{1c}^{le} = 0.682742*HBA0 + 0.054377*RHI1 + 1.553277$, wherein

HBA0 is a previous reference HbA_{1c} reading taken about a second predetermined period prior to the estimate, wherein

RHI1 = is the High BG Index of claim 200; or

$$d) \text{ HbA}_{1c} = 0.41046 \cdot \text{BGMM} + 4.0775$$

wherein BGMM1 is the average BG (mmol/l) of claim 200.

206. (previously presented) The method of claim 205, wherein said second predetermined duration is about three months.
207. (previously presented) The method of claim 205, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.
208. (previously presented) The method of claim 205, wherein said second predetermined duration ranges from about 2.5 months to six months.
209. (currently amended) The method of claim 205, wherein the validation of the sample using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:
- a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;
 - b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;

- c) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio $(RLO1/RHI1) \geq$ about 0.005),
wherein
RLO1 is the Low BG Index of claim 200
RHI1 is the High BG Index of claim 200; or
- d) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio $(N06 \geq$ about 3%).
wherein
N06 is the percentage of readings during the night of claim 200.
210. (previously presented) The method of claim 209,
wherein said third predetermined duration is at least 35 days.
211. (previously presented) The method of claim 209,
wherein said third predetermined duration ranges from about 35 days to about 40 days.
212. (previously presented) The method of claim 209,
wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.
213. (currently amended) The method of claim 205, wherein the validation of the sample using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

- a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and
- b) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio $(RLO1/RHI1) \geq$ about 0.005),
wherein
RLO1 is the Low BG Index of claim 149
RHI1 is the High BG Index of claim 200; or
- c) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio $(NO6 \geq$ about 3%),
wherein
NO6 is the percentage of readings during the night of claim 200.
214. (previously presented) The method of claim 213,
wherein said third predetermined duration is at least about 35 days.
215. (currently amended) A system for evaluating the HbA_{1c} of a patient without the need for prior HbA_{1c} information based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:
- a database component operative to maintain a database identifying said BG data; and
- a processor programmed to:
- ~~prepare the data for estimating HbA_{1c} using a predetermined sequence of mathematical formulas~~

~~defined as:~~

pre-process the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data,
validate a sample of the collected BG data via sample selection criteria, and
estimate HbA_{1c} from said derived BG data if the sample is valid; and

output the estimate to a user.

216. (previously presented) The system of claim 215, wherein said first predetermined duration is about 60 days.
217. (previously presented) The system of claim 215, wherein said first predetermined duration ranges from about 45 days to about 75 days.
218. (previously presented) The system of claim 215, wherein said first predetermined duration ranges from about 45 days to about 90 days.
219. (currently amended) The system of claim 215, wherein the preprocessing of the data ~~for each patient~~ comprises:
conversion of plasma data to whole blood BG mg/dl;
conversion of BG measured in mg/dl to units of mmol/l;
and
computing Low Blood Glucose Index (RL01) and High Blood Glucose Index (RH11).
220. (currently amended) The system of claim 215, wherein the preprocessing of the data ~~for each patient using~~

~~predetermined mathematical formulas defined~~
~~as~~ comprises:

conversion of plasma to whole blood BG mg/dl via
 $BG = PLASBG \text{ (mg/dl)} / 1.12$;

conversion of BG measured in mg/dl to units of mmol/l
via $BGMM = BG / 18$; and

computing Low Blood Glucose Index (RLO1) and High
Blood Glucose Index (RHI1) using a predetermined
mathematical formula defined as:

$Scale = [\ln(BG)]^{1.0845} - 5.381$, wherein BG is
measured in units of mg/dl,

$Risk1 = 22.765(Scale)^2$, wherein

$RiskLO = Risk1$ if (BG is less than about 112.5) and
therefore risk of LBGI exists, otherwise
 $RiskLO = 0$, and

$RiskHI = Risk1$ if (BG is greater than about 112.5)
and therefore risk of HBGI exists, otherwise
 $RiskHI = 0$,

$BGMM1$ = average of BGMM per patient,

$RLO1$ = average of RiskLO per patient,

$RHI1$ = average of RiskHI per patient,

$L06$ = average of RiskLO computed only for
readings during the night, otherwise missing if
there are no readings at night,

$N06$, $N12$, $N24$ are percentage of SMBG readings in
time intervals,

$Nc1$ = total number of SMBG readings in the first
predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

221. (currently amended) A system for evaluating the HbA_{1c} of a patient without the need for prior HbA_{1c} information based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient;

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

~~prepare the data for estimating HbA_{1c} using a predetermined sequence of mathematical formulas defined as:~~

pre-process the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data;

validate a sample of the collected BG data via sample selection criteria; [[and]]

estimate HbA_{1c} from said derived BG data if the sample is valid; and

output the HbA_{1c} estimate to a user.

222. (previously presented) The system of claim 221, wherein said first predetermined duration is about 60 days.
223. (previously presented) The system of claim 221, wherein said first predetermined duration ranges from

- about 45 days to about 75 days.
224. (previously presented) The system of claim 221, wherein said first predetermined duration ranges from about 45 days to about 90 days.
225. (currently amended) The system of claim 221, wherein the preprocessing of the data ~~for each patient~~ comprises:
- conversion of plasma data to whole blood BG mg/dl;
 - conversion of BG measured in mg/dl to units of mmol/l;
 - and
 - computing Low Blood Glucose Index (RL01) and High Blood Glucose Index (RHI1).
226. (currently amended) The system of claim 221, wherein the preprocessing of the data ~~for each patient using predetermined mathematical formulas~~ is defined as:
- conversion of plasma to whole blood BG mg/dl via $BG = PLASBG \text{ (mg/dl)} / 1.12$;
 - conversion of BG measured in mg/dl to units of mmol/l via $BGMM = BG / 18$; and
 - computing Low Blood Glucose Index (RL01) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:
$$Scale = [\ln(BG)]^{1.0845} - 5.381, \text{ wherein BG is measured in units of mg/dl,}$$
$$Risk1 = 22.765(Scale)^2, \text{ wherein}$$
$$RiskLO = Risk1 \text{ if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise}$$
$$RiskLO = 0, \text{ and}$$

RiskHI=Risk1 if (BG is greater than about 112.5)
and therefore risk of HBGI exists, otherwise
RiskHI=0,

BGMM1 = average of BGMM per patient,

RL01 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for
readings during the night, otherwise missing if
there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in
time intervals,

NC1 = total number of SMBG readings in the first
predetermined duration; and

NDAYS = number of days with SMBG readings in the
first predetermined duration.